

# COLLECTIVE EXPERT APPRAISAL: SUMMARY AND CONCLUSIONS

## Regarding the expert appraisal for recommending occupational exposure limits for chemical agents

### concerning the assessment of measurement methods for dust without specific effects (DWSE)

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This document summarises the work of the Expert Committees “Health Reference Values” (HRV Committee) and the Working Group on Metrology.

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## Presentation of the issue

On 18 November 2015, ANSES received a formal request from the Directorate General for Labour (DGT) to conduct the expert appraisal work required for revising occupational exposure limits (OELs) for so-called dust without specific effects (DWSE), i.e. “that is not capable alone of causing any effect on the lungs or any other organ or system of the human body other than an overload effect” (DGT Circular of 9 May 1985).

France currently has binding regulatory values for DWSE (Article R.4222-10 of the Labour Code): an 8-hour time-weighted average (TWA) exposure value for total dust of  $10 \text{ mg}\cdot\text{m}^{-3}$  and an 8-hour TWA exposure value for respirable dust of  $5 \text{ mg}\cdot\text{m}^{-3}$ .

The DGT asked ANSES to re-assess these values as a matter of priority, following publication of ANSES’s opinion on “Chemical air pollution in underground railway areas and the associated health risks for workers”.

As this request was classified as a priority, the approach adopted to recommend new occupational exposure limits (OELs) relied on a critical analysis of the existing international scientific reports and appraisals, and not on an exhaustive analysis of the scientific literature according to the methodology usually applied.

In November 2019, ANSES published an opinion and an expert appraisal report focusing only on the health effects associated with exposure to DWSE and recommended, based on the existing scientific appraisals, the following occupational exposure limits:

- 8h-OEL for the inhalable fraction:  $4 \text{ mg}\cdot\text{m}^{-3}$
- 8h-OEL for the respirable fraction:  $0.9 \text{ mg}\cdot\text{m}^{-3}$

This document is a response regarding the assessment of methods for measuring DWSE with regard to these recommendations. It supplements the work published in November 2019 recommending OELs based on a critical analysis of the existing international scientific reports and appraisals.

## Scientific background

The French system for establishing OEL values has three clearly distinct phases:

- independent scientific expert appraisal (the only phase entrusted to the Agency);
- proposal by the Ministry of Labour of a draft regulation for the establishment of limit values, which may be binding or indicative;
- stakeholder consultation during the presentation of the draft regulation to the French Steering Committee on Working Conditions (COCT). The aim of this phase is to discuss the effectiveness of the limit values and if necessary to determine a possible implementation timetable, depending on any technical and economic feasibility problems.

The organisation of the scientific expertise phase required for the establishment of Occupational Exposure Limits (OELs) was entrusted to AFSSET in the framework of the 2005-2009 Occupational Health Plan (PST) and then to ANSES after AFSSET and AFSSA merged in 2010.

The Committee also evaluates the applicable reference methods for measuring exposure levels in workplace atmospheres. The quality of these methods and their applicability to the measurement of exposure levels for comparison with an OEL are assessed, particularly with regards to their compliance with the performance requirements in the NF-EN 482 Standard and their level of validation.

## Organisation of the expert appraisal

ANSES entrusted examination of this request to the Expert Committee on Health Reference Values (HRV Committee) and to Working Group on Metrology.

The methodological and scientific aspects of the work of this group were regularly submitted to the Expert Committee.

The report produced takes into account the comments and additional information provided by the members of the Expert Committee.

This expert appraisal was therefore conducted by a group of experts with complementary skills. It was carried out in accordance with the French Standard NF X 50-110 "Quality in Expertise Activities".

## Prevention of risks of conflicts of interest

ANSES analyses the links of interest declared by the experts prior to their appointment and throughout the work, in order to avoid potential conflicts of interest with regard to the matters dealt with as part of the expert appraisal.

The experts' declarations of interests are made public *via* the ANSES website ([www.anses.fr](http://www.anses.fr)).

## Description of the method

For the assessment of the methods for measuring exposure levels in the workplace:

An assessment report of the measurement methods was prepared by the Working Group on Metrology and submitted to the HRV Committee, for comments and validation. Several ANSES employees also contributed to this work.

The various protocols for measuring DWSE in workplace atmospheres were identified and grouped together according to the methods used. These methods were then assessed and classified based

on the performance requirements set out particularly in the French Standard NF EN 482: "Workplace atmospheres - General requirements for the performance of procedures for the measurement of chemical agents" and the decision-making criteria listed in the methodology report (ANSES, 2020). The list of the main sources consulted is detailed in the methodology report (ANSES, 2020).

These methods were classified as follows:

- Category 1A: recognized and validated methods (all of the performance criteria are met);
- Category 1B: partially validated methods (the essential performance criteria are met);
- Category 2: indicative methods (essential criteria for validation are not clear enough or else the method requires adjustments that need to be validated);
- Category 3: the methods are not recommended (essential criteria for validation are lacking or inappropriate). This category encompasses unsuitable methods for which essential validation criteria have not been met, and non-assessable methods (falling in Category 3\*) for which essential validation criteria have not been documented.

A detailed comparative study of the methods in Categories 1A, 1B and 2 was conducted with respect to their various validation data and technical feasibility, in order to recommend the most suitable method(s) for measuring concentrations for comparison with OELs.

Concerning the measurement of DWSE concentrations, certain evaluation criteria do not apply: determination of the sampling rate for passive media, interferences, and adsorption/desorption efficiency. The essential criteria to be considered deal with the compliance of sampling devices for the conventional inhalable or respirable fraction, the influence of environmental conditions, trapping capacity, limits of quantification, measurement range, and uncertainties.

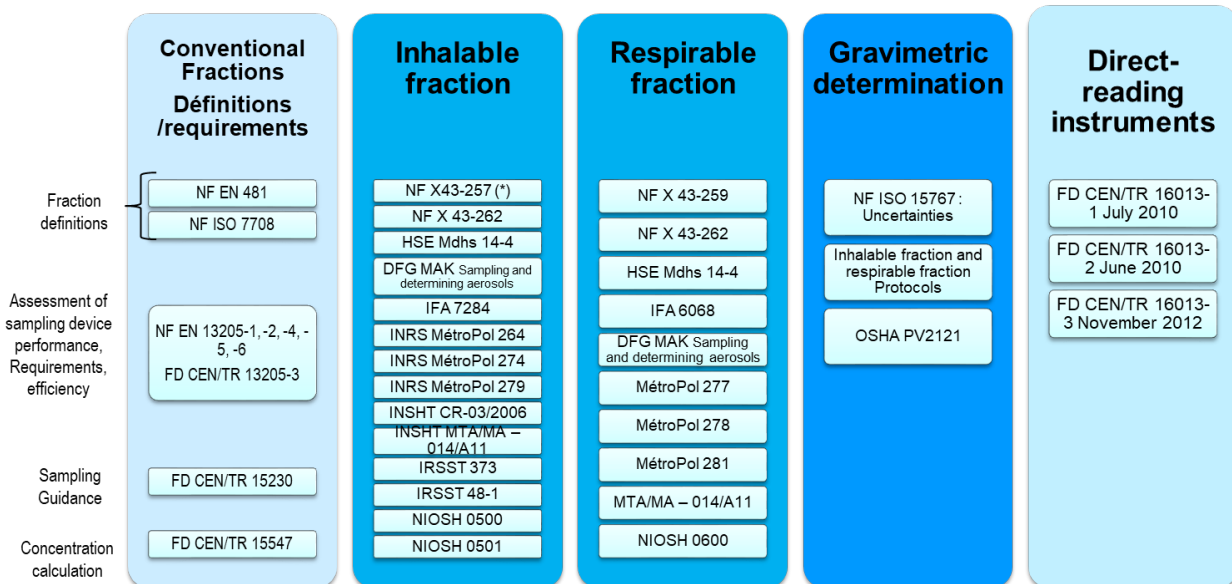
That is why the performance of the sampling devices described in the identified protocols with regard to the conventional inhalable and respirable fractions was initially analysed. A literature review was also conducted to supplement these data (queries performed in the Scopus database, in December 2017 and March 2018; keywords: aerosol, sampler, inhalable, respirable, occupational, internal, capsule, accu-cap; without date limits). The performance of the sampling devices with regard to the conventional inhalable or respirable fraction was assessed based on all of these data (protocols + literature), and care was taken to evaluate and analyse the bias of each sampler compared with the conventional curve. Limits of quantification, trapping capacity and measurement ranges were then assessed through gravimetric performance.

The report, as well as the summary and conclusions of the collective expert appraisal were adopted by the Expert Committee on Health Reference Values on 19 March 2020.

This collective expert appraisal work and the summary report were submitted to public consultation from 07/05/2020 to 05/06/2020. No comments were received. The Health Reference Values Committee adopted this finalised version on 26<sup>th</sup> June 2020.

## Results of the collective expert appraisal on the assessment of methods for measuring DWSE in connection with the 8h-OELs recommended by ANSES

Figure 1 shows the types of protocols identified in connection with the measurement of DWSE concentrations (inhalable and respirable fractions).



(\*) The NF X 43-257 standard does not describe the sampling of the inhalable fraction, but rather the sampling of aerosols using a cassette (4mm orifice). However, the method described in this standard is used in many countries to determine the inhalable fraction of aerosols.

Figure 1: Inventory of protocols

The identified methods use air sampling with a sampling device for the inhalable fraction or the respirable fraction on various types of media. There are also devices for simultaneously sampling the inhalable and respirable fractions. The collection medium then undergoes a gravimetric analysis. Therefore, the main difference between these methods lies in the sampling device used. Table 1 shows the various methods identified for measuring DWSE as well as the dust sampling devices mentioned in the identified protocols:

- Sampling devices for the inhalable fraction: Button, 37 mm closed-faced cassette (CFC), CFC + internal capsule, CIP 10-I, 37 mm Flying saucer, GSP 3.5 or CIS, GSP-10, IOM, PAS-6, 7-hole.
- Sampling devices for the respirable fraction: Dorr-Oliver cyclone (DO cyclone), Higgins-Dewell cyclone (HD cyclone), GS1/GS3 cyclone, GK2.69 cyclone, GK4.162 cyclone, AI cyclone, CIP 10-R, high-flow-rate samplers (PGP10, BGI GK4.162 cyclone, PPI8 impactor).
- Devices enabling the simultaneous sampling of the inhalable and respirable fractions: CIS multi-fraction respirable, IOM 'multidust' or dual fraction respirable, Perspec, Respicon, Marple impactor and Mini-Moudi impactor.

Devices for the fixed-point sampling of the inhalable or respirable fraction were not assessed because they do not enable assessment of occupational exposure. Direct-reading devices for measuring DWSE (photometry, optical particle counting) were not assessed either because,

although they enable the near-instant monitoring of concentrations as well as the monitoring of particle size distributions, they currently have limitations that keep them from being used for monitoring compliance with a regulatory OEL, in particular the need for additional calculations to estimate mean exposure for comparison with an OEL.

Table 1: Details of DWSE measurement methods

Sampling device	Fraction of interest	Sampling medium	Sampling flow rate (L.min <sup>-1</sup> )	Protocols
Button	Inhalable	25 mm diameter PVC or EC membrane	4	FD CEN/TR 15230, HSE MDHS 14-4, INSHT CR 003 A06, INSHT MTA/MA 014/A11
37 mm closed-faced cassette (CFC)	Inhalable Total fraction (US-Canada)	37 mm PVC membrane, glass fibre or quartz fibre filters, mixed cellulose ester (MCE), Teflon membrane	1 to 2	INRS MétroPol M-274 + INRS MétroPol closed cassette, NIOSH 0500, IRSST 48-1, NF X43-257
CFC and internal capsule	Inhalable	37 mm PVC membrane (2 to 5 µm), sealed to a PVC capsule Capsule sealed to an EC membrane	1 to 2	NIOSH 0501, INRS MétroPol M-274, INRS MétroPol cassette, NF X43-257
CIP 10-I V.1 or V.2	Inhalable	Polyurethane foam	10	INRS MétroPol M-279, INRS MétroPol M-281, INRS MétroPol CIP 10, FD CEN/TR 15230, INSHT CR-03/2006, INSHT MTA/MA 014/A11
37 mm flying saucer	Inhalable	37 mm PVC membrane	2	OSHA PV 2121
GSP-3.5 <sup>1</sup> or CIS	Inhalable	37 mm glass fibre filter	3.5	HSE MDHS 14/4, INSHT CR-03/2006, INSHT MTA/MA 014/A11, FD CEN/TR 15230, BIA 7284, DFG MAK sampling aerosols
GSP-10 <sup>2</sup>	Inhalable	37 mm glass fibre filter	10	INSHT MTA/MA 014/A11, BIA 7284, FD CEN/TR 15230
IOM	Inhalable	25 mm diameter filter + filter holder (made of conductive plastic or stainless steel) Glass fibre filters, cellulose ester (CE), PVC, polycarbonate or gelatine membrane	2	HSE MDHS 14/4, FD CEN/TR 15230, INSHT CR-03/2006, INSHT MTA/MA 014/A11 IRSST MA-373
PAS-6	Inhalable	25 mm filter	2	FD CEN/TR 15230, INSHT CR 003 A06, INSHT MTA/MA 014/A11
7-hole (or multi-orifice)	Inhalable	25 mm filter	2	HSE MDHS 14/4
DO cyclone	Respirable	37 mm (5 µm) PVC membrane, 37 mm glass fibre or quartz fibre filters	1.7 Optimised: 1.5	MétroPol 278, INSHT MTA-MA 014-A11, OSHA PV2121, NIOSH 0600, FD CEN/TR 15230 Lidén & Kenny (1993), Görner <i>et al.</i> , 2001, Gautam <i>et al.</i> , 1997
Higgins-Dewell cyclones	FSP 10	37 mm (8 µm) CE membrane, 37 mm (5 µm) PVC membrane, 37 mm or 25 mm glass fibre filters	10	DFG MAK, IFA 6065
	SIMPEDS-FSP2		Optimised: 11.2	Lee <i>et al.</i> (2010)
	SKC Plastic		2.2	NIOSH 0600, HSE MDHS 14-4, FD CEN/TR 15230, INSHT MTA-MA 014-A11
			3	SKC Plastic cyclone notice (2019)

<sup>1</sup> Sometimes also denoted PGP-GSP (FD CEN/TR 15230)

<sup>2</sup> Also denoted PGP-GSP10 (FD CEN/TR 15230)

Sampling device	Fraction of interest	Sampling medium	Sampling flow rate (L.min <sup>-1</sup> )	Protocols
GS1 cyclone	Respirable	37 mm (8 µm) CE membrane, 37 mm (5 µm) PVC membrane, 37 mm or 25 mm glass fibre filters	2	HSE MDHS 14-4, FD CEN/TR 15230, INSHT MTA-MA 014-A11
GS3 cyclone	Respirable		2.75 Optimised: 2.5-2.6	HSE MDHS 14-4, FD CEN/TR 15230, INSHT MTA-MA 014-A11
GK2.69 cyclone	Respirable	37 mm (8 µm) CE membrane, 37 mm (5 µm) PVC membrane, 37 mm glass fibre filters	4.2	HSE MDHS 14-4, FD CEN/TR 15230, INSHT MTA-MA 014-A11
GK4.162	Respirable		Optimised: 4.4 9	Kenny & Gussman (1997), Lee <i>et al.</i> (2010) Thorpe (2011)
AI cyclone	Respirable	37 mm (5 µm) PVC membrane, 25 mm glass fibre filter	2.5 2.67	NIOSH 0600, HSE MDHS 14-4, FD CEN/TR 15230 Chen <i>et al.</i> (1999)
CIP 10-R	Respirable	Polyurethane foam	10	MétroPol 281 + MétroPol Sheet CIP 10, FD CEN/TR 15230, DFG MAK
High-flow-rate samplers (PGP10 <sup>3</sup> , BGI GK4.162 cyclone, PPI8 impactor)	Respirable	37 mm (5.0 µm) PVC filter	8 to 10	HSE MDHS 14-4, FD CEN/TR 15230
CIS multi-fraction respirable	Inhalable Thoracic Respirable	37 mm glass fibre filter + polyurethane foam	3.5	HSE MDHS 14/4
IOM 'multidust' or dual fraction respirable	Inhalable Respirable	Polyurethane foam and 25 mm filter in the filter holder Glass fibre filters, cellulose ester (CE), PVC, polycarbonate or gelatine membrane	2	FD CEN/TR 15230, HSE MDHS 14/4, INSHT MTA/MA 014/A11
Perspec	Inhalable Respirable Thoracic	50 mm filter – Specially shaped selectors are used for the various fractions	2	FD CEN/TR 15230, Kenny, Aitken <i>et al.</i> , 1997, Woehkenberg <i>et al.</i> , 1998
Respicon	Inhalable Thoracic Respirable	37 mm glass fibre filter or 37 mm PVC membranes (pore size: 5.0 µm)	3.11	FD CEN/TR 15230, HSE MDHS 14/4, INSHT MTA/MA 014/A11 TSI brochure
Marple impactor Mini-Moudi impactor	Inhalable Thoracic Respirable	Different types of filters	2 2	HSE MDHS 14-4

<sup>3</sup> Also denoted PGP-FSP10 (FD CEN/TR 15230)

**Preliminary remarks:**

Concerning the assessment of sampling efficiency with regard to the conventional inhalable and respirable fractions:

- not all of the necessary information is available in the protocols or the literature. The overall bias across the entire particle size range of interest is often not provided; however, for certain sampling devices, it was possible to calculate biases for various particle size classes;
- **to evaluate the available data, a qualitative analysis of bias was therefore undertaken, considering an arbitrary value  $\pm 25\%$  to assess deviations from the conventional curve and classify sampling devices based on experimental laboratory studies;**
- the influence of certain parameters on sampling efficiency (wind speeds, especially low wind speeds frequently encountered in workplace atmospheres ( $v < 0.5 \text{ m}\cdot\text{s}^{-1}$ ), electric charge of the aerosol, deposition on walls, orientation of the device) was also discussed, whereas the influence of other parameters (composition of the aerosol, inter-specimen variability, surface treatment, etc.) was not assessed due to a lack of data;
- the conventional inhalable fraction was determined for relatively high wind speeds (up to  $4 \text{ m}\cdot\text{s}^{-1}$ ). Since the wind speeds currently encountered in indoor workplaces are much lower (generally below  $0.3 \text{ m}\cdot\text{s}^{-1}$ ; Baldwin *et al.*, 1998), several authors have attempted to define inhalability in calm air (Aitken *et al.*, 1999, Sleeth *et al.*, 2011). However, this has not been covered by any convention and is not currently standardised. Therefore, the various sampling devices were only assessed with regard to the conventional inhalable fraction, regardless of the wind speed at which they were tested.

Concerning the gravimetric analysis:

- the media that are most commonly used for air sampling in the workplace and associated with the identified sampling devices for the inhalable and respirable fractions are: quartz fibre or glass fibre filters (depth filters), acetate or mixed cellulose ester (CE) membranes, PVC membranes, cups for CIP 10 (polyurethane foam), IOM cassettes, capsules sealed to a membrane, or PTFE (Teflon®) membranes. The latter were excluded from this expert appraisal because they are highly sensitive to electrostatic charges (DFG MAK sampling aerosols). Moreover, this type of membrane is insoluble, which can be problematic when the analysis of the collected dust requires the medium to be dissolved. The composition of membrane-sealed capsules can vary (made fully of cellulose ester, fully of PVC, or with a PVC capsule and a cellulose ester membrane);
- the limits of quantification taken into account (data from the identified protocols and additional literature queries) for the assessment of performance should be considered as providing orders of magnitude since, for the same medium, these values depend not only on criteria such as the environmental conditions, the sensitivity of the balance, etc., but also on the sampling time, the suppliers of the media, and even the batches used;
- the approximate maximum mass that can be deposited on media depending on their nature and size was determined based on the retention index<sup>4</sup> available in the identified protocols.

**Results of the assessment of measurement methods for DWSE – inhalable fraction****Summary on the performance of sampling devices with regard to the inhalable convention**

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<sup>4</sup> Retention index: areal density of material collected on a filter that should not be exceeded to limit impact losses of material, during transport for example.



At wind speeds of around  $0.5 \text{ m}\cdot\text{s}^{-1}$  or lower (the most common scenario in workplace atmospheres (Baldwin *et al.*, 1998)):

- IOM, Button and 7-hole overestimated the conventional fraction;
- CFC alone underestimated the conventional fraction starting at 20- 30  $\mu\text{m}$ ;
- CFC + internal capsule, GSP/CIS, CIP 10-I-V2 and PAS-6 underestimated the conventional fraction starting at around 40-50  $\mu\text{m}$ ;
- the sensitivity of IOM, Button, CFC, 7-hole and GSP to their orientation with respect to the airflow direction (facing, perpendicular or opposite) was studied and, regardless of the device, a  $90^\circ$  or  $180^\circ$  orientation reduced capture efficiency and led to under-sampling with regard to the conventional fraction. CFC was also highly sensitive to the device's inlet inclination: a  $45$  to  $90^\circ$  downward inclination, even when CFC was oriented to face the airflow, resulted in lower capture efficiency than when the inlet was horizontal;
- the lower the wind speed:
  - the greater the increase in sampling efficiency for IOM, Button and GSP, resulting in greater over-sampling, as well as for CFC + internal capsule, resulting in a lower negative bias compared with the conventional curve;
  - and the greater the decrease in sampling efficiency for CIP 10-I-V2 and CFC alone, resulting in a higher negative bias compared with the conventional curve.

The sampling efficiency of PAS-6 was not studied for wind speeds below  $0.5 \text{ m}\cdot\text{s}^{-1}$ , nor was the effect of orientation regardless of wind speed.

At higher wind speeds ( $1$  to  $4 \text{ m}\cdot\text{s}^{-1}$ ):

- in studies using rotating manikins or averaging the results according to the various orientations, a decrease in sampling efficiency was observed for IOM, 7-hole, GSP and CFC alone. However, when these devices were oriented to face the airflow, they showed an increase in sampling efficiency, with the exception of CFC alone. The sampling efficiency of CFC + internal capsule was not studied for wind speeds above  $0.5 \text{ m}\cdot\text{s}^{-1}$ . Concerning CIP 10-I-V2, its sampling efficiency was better at a speed of  $1 \text{ m}\cdot\text{s}^{-1}$  than in calm air (the bias compared with the convention decreased). Button underestimated the conventional fraction;

Regardless of the study, CFC alone was the device that had the highest under-sampling biases compared with the inhalable convention for particle sizes above 20-30  $\mu\text{m}$ , with a negative bias below -25%.

The sampling efficiency of Button was less dependent on wind speed than for IOM, CFC alone and GSP. This efficiency was relatively similar to that of IOM.

Due to a lack of validation data, the “flying saucer” device was not assessed for the sampling of the inhalable fraction.

### Summary on the gravimetric analysis

PVC membranes and quartz fibre filters were the most suitable sampling media and were almost systematically able to reach  $0.1\cdot 8\text{h-OEL}$  for the entire range of LQ values considered, regardless of the membrane diameter and the flow rates used, and thus regardless of the sampling device.

Due to the retention coefficient of PVC membranes and quartz fibre filters, only devices with a sampling rate of  $1$  to  $2 \text{ L}\cdot\text{min}^{-1}$ , i.e. IOM, CFC and CFC + internal capsule, can be used for 8h

sampling at 2\*8h-OEL. For devices with a rate of 3.5 or 4 L·min<sup>-1</sup> (GSP, CIS and Button), it will be necessary to take two 4h samples.

CIP 10 can also be used to take 8h samples at 10 L·min<sup>-1</sup>.

It should be noted that PVC membranes are electrostatic under certain conditions. Appropriate corrections are therefore necessary (blank weighings).

In general, CE membranes are unable to reach the range of 0.1 to 2 times the 8h-OEL except when used with CFC + internal capsule at 2 L·min<sup>-1</sup>.

Quartz and glass fibre filters should not be favoured for a gravimetric analysis due to “degradation” (fibre losses during handling), except when used with IOM and when the IOM cassette + filter are weighed together.

## **Results of the assessment of measurement methods for DWSE – respirable fraction**

### **Summary on the performance of sampling devices with regard to the respirable convention**

Most of the experimental studies assessed these devices with aerosols with particle sizes of up to around 10 µm and for wind speeds ranging from 0.15 to 4 m·s<sup>-1</sup>.

At calm wind speeds (of around 0.5 m·s<sup>-1</sup> or lower):

- DO, HD and GK cyclone devices overestimated the conventional fraction for particle diameters below 4 µm and underestimated the conventional fraction for particle diameters above 4 µm;
- CIP 10-R underestimated the conventional fraction for particle diameters below 2 µm;
- there are no experimental studies in calm air for the GS3 cyclone.

At higher wind speeds (1 to 4 m·s<sup>-1</sup>):

- the sensitivity of the DO cyclone to wind speed and to orientation with respect to airflow (facing, perpendicular or opposite) was studied. The higher the wind speed, the greater the decrease in sampling efficiency for the DO cyclone, resulting in a higher negative bias compared with the conventional curve. 90° and 180° orientations also led to under-sampling of the respirable fraction (lower cut-off diameters and increase in bias);
- the GS3 cyclone, studied only for high wind speeds, showed better efficiency with regard to the respirable fraction and was not sensitive to the device's orientation. The greater the increase in wind speed, the greater the increase in bias, with under-sampling of the respirable fraction;
- there are no experimental studies at high wind speeds for HD and GK cyclones and the CIP 10-R device.

The effects of deposition on walls and electrostatic charges were studied for DO and GS cyclones. The DO cyclone was highly sensitive to these factors and led to a lower capture efficiency.

Performance in terms of the cut-off diameters of 15 sampling devices, 11 of which used cyclones, was assessed in calm air for polydisperse coal dust (Görner *et al.*, 2001). The authors showed that ± 1 µm for the 50% cut-off diameter (D50) could be reasonably accepted and that the D50 could be improved by adapting the pump flow rate for most of the devices. However, the lower the flow rate, the harder it was to adapt it. They recommended the systematic use of bias and accuracy maps to be able to estimate over- or under-sampling.

### **Summary on the gravimetric analysis**

PVC media with a diameter of 25 mm were suitable and were almost systematically able to reach 0.1 times the 8h-OEL for the entire range of LQ values and flow rates considered. The sole exception was for flow rates of 1.5 and 1.7 L·min<sup>-1</sup>. However, these LQ values are relatively old and depend on the weighing conditions. Since they are very close to one-tenth of the 8h-OEL, they should be optimised to reach this threshold.

PVC membranes with a 37 mm diameter as well as glass or quartz fibre filters (25 or 37 mm diameter) were suitable when the lower limit of the range of LQ values considered was taken into account. Quartz or glass fibre filters should not be favoured for a gravimetric analysis due to their sensitivity to “degradation” (fibre loss during handling).

Concerning PU foams and CE membranes, the limit of quantification was unable to reach one-tenth of the 8h-OEL.

### **Summary on the efficiency of devices simultaneously sampling the inhalable and respirable fractions**

Only the HSE MDHS 14/4 protocol mentions several devices that are capable of simultaneously measuring several conventional fractions: IOM dual fraction, CIS multi-fraction respirable sampler, and the Respicon, Mini Moudi, Sioutas and Marple impactors.

No experimental studies have assessed the sampling efficiency of these devices with regard to the conventional inhalable and respirable fractions. Therefore, devices that simultaneously sample the inhalable and respirable fractions are not recommended, for measuring either the inhalable or the respirable fraction.

The available data compare several devices with one another.

The IOM dual sampler is sensitive to dustiness, as the D50 mean cut-off diameter varies with the loading of the PU foam upstream of the collection filter.

Multi-stage impactors requiring the weighing of several filters to obtain the respirable fraction involve major uncertainties related to cumulated weighing errors.

The CIS multi-fraction respirable sampler could not be assessed due to a lack of identified studies documenting its performance.

## **Conclusions of the collective expert appraisal**

The measurement of DWSE concentrations for comparison with the inhalable or respirable 8h-OEL involves aerosol sampling followed by a gravimetric analysis.

Various sampling devices for the inhalable fraction and the respirable fraction are described through the identified protocols. The performance of these devices in terms of their collection efficiency with regard to the inhalable and respirable conventions was determined in experimental laboratory studies. Various parameters, in particular the nature of the dust and the environmental conditions (particle size distribution, dust level, wind speed, orientation of the device), influence sampling efficiency with regard to the conventional inhalable and respirable fractions.

***Based on the existing standards and protocols as well as the experimental studies, the various devices show varying degrees of sampling efficiency, which depends on the aerosol particle size and the environmental conditions, in particular wind speed and the orientation of the device.***

***No devices perfectly meet the requirements in terms of sampling efficiency with regard to the conventional inhalable or respirable fractions in all environmental situations and across the entire particle size range of interest.***

***In the interests of prevention, the CES decided to favour devices that overestimate the conventional fractions in question (and therefore to downgrade those that underestimate these same fractions).***

### **8h-OEL – inhalable fraction:**

Concerning the sampling devices for the inhalable fraction assessed with regard to the “compliance for the conventional inhalable fraction” criterion:

- **CFC alone, PAS-6 and CIP 10-I-V1 are classified in Category 3 and are therefore not recommended for sampling the inhalable fraction.** This is because:
  - CFC alone, although it is closest to the conventional fraction for aerosols with particle sizes < 20-30 µm, shows major under-sampling starting at 20-30 µm, regardless of the wind speed. It has the highest under-sampling of all the assessed devices. A decrease in sampling efficiency is observed at the lowest wind speeds as well as at those greater than or equal to 1 m·s<sup>-1</sup>. This sampling device is also particularly sensitive to orientation, both horizontally and vertically. Therefore, the collection efficiency of CFC (alone) is not acceptable;
  - the behaviour of PAS-6 with regard to the conventional inhalable fraction at wind speeds below 0.5 m·s<sup>-1</sup> is not studied, nor is the influence of this device's orientation with respect to airflow on sampling efficiency;
  - CIP 10-I-V1 underwent design changes aiming to improve its performance. Version 2 has greater sampling efficiency and a lower bias with regard to the conventional inhalable fraction.
- **Button, CFC + internal capsule, CIP 10-I-V2, GSP-3.5, IOM and 7-hole are classified in Category 2 and are recommended for sampling the inhalable fraction.** This is because:
  - the biases observed in conditions similar to workplace atmospheres (wind speed ≤ 0.5 m·s<sup>-1</sup>) with regard to the convention are lower than those observed with CFC alone;
  - the underestimation of the conventional fraction starts for larger particle sizes (around 40 to 50 µm for GSP-3.5 and CFC + internal capsule versus 20-30 µm with CFC alone);
  - Button seems to be more accurate and less sensitive to wind speed than the other devices;
  - Button and IOM tend to overestimate the conventional fraction. 7-hole overestimate it in conditions of orientation facing the airflow and at low wind speeds.

**Concerning the gravimetric analysis**, this is not a limiting factor provided that PVC membranes and quartz fibre filters are used for devices other than CIP 10-I-V2, and provided that the weighing recommendations described in Section 4.3.1. of the collective expert appraisal report are followed. **The various sampling devices for the inhalable fraction are all able to cover the range of 0.1 to 2 times the 8h-OEL defined for the inhalable fraction, with 8h sampling or with two successive 4h samplings. PVC membranes shall be favoured due to potential fibre loss when handling quartz or glass fibre filters.**

### **8h-OEL – respirable fraction:**

Concerning the sampling devices for the respirable fraction assessed with regard to the “compliance for the conventional fraction” criterion:

- **GS-1 cyclones and the CIP 10-R cup are classified in Category 3 and are therefore not recommended for sampling the respirable fraction.** This is because:
  - the GS-1 device has not undergone experimental studies assessing its performance;
  - CIP10-R has low efficiency for collecting particles with diameters below 2 µm.
- **Higgins-Dewell (HD) cyclones, which have different geometries and flow rates, as well as Dorr-Oliver (DO), GK2.69 and 4.162, AI, and GS-3 cyclones, are classified in Category 2 and are recommended for measuring the respirable fraction.** This is because:
  - minor deviations from the conventional curve are observed with overestimation for particles with diameters below 4 µm and underestimation for particles with diameters between 4 and 10 µm;
  - the most commonly described and used sampling methods rely on cyclones (HD, DO, AI, GS-3). Optimisation of the sampling rate was studied for these devices, for better comparison with the conventional respirable fraction through improved performance and is therefore recommended as part of this expert appraisal;
  - when electrostatic-sensitive cassettes are used, there may be deposits on the walls;
  - Higgins-Dewell HD (SIMPEDS, FSP2, Casella plastic, SKC plastic cyclone, BGI4L, FSP10) cyclones have not been studied in terms of the orientation of the device, the influence of relative humidity, or the type, concentration and electrostatic charge of the aerosol, unlike the DO cyclone;
  - high-flow-rate cyclone devices (FSP10, GK2.69 and GK4.162) can induce a greater pressure drop and can be more cumbersome due to the higher weight of the sampling pump.

Concerning the gravimetric analysis:

- PVC media with a diameter of 25 mm are suitable and are almost systematically able to reach 0.1 times the 8h-OEL for the entire range of LQ values and flow rates considered. The sole exception is for flow rates of 1.5 and 1.7 L·min<sup>-1</sup>, for which the LQ should be optimised;
- PVC membranes with a 37 mm diameter as well as glass or quartz fibre filters (25 or 37 mm diameter) are suitable when the lower limit of the range of LQ values considered is taken into account;
- quartz or glass fibre filters shall not be favoured for a gravimetric analysis due to their sensitivity to humidity and “degradation” (fibre loss during handling);
- concerning PU foams, the limit of quantification is unable to reach one-tenth of the 8h-OEL.

**Therefore, sampling devices for the respirable fraction are able to cover the range of 0.1 to 2\*8h-OEL, provided that the weighing recommendations described in Section 4.3.1. of the collective expert appraisal report are followed, with 8h sampling or with two successive 4h samplings. Only CIP 10-R is unable to cover 0.1 to 2 times the 8h-OEL defined for the respirable fraction.**

**Concerning devices that simultaneously sample the inhalable and respirable fractions, no experimental studies have assessed their sampling efficiency with regard to the conventional inhalable and respirable fractions. These devices could not be assessed and are therefore classified in Category 3<sup>(\*)</sup>. They are not recommended, for measuring either the inhalable or the respirable fraction.**

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(\*) *Sampling devices that cannot be assessed due to a lack of validation data*

**Thus, in light of the data currently available comparing sampling performance with regard to the conventional fractions and of the gravimetric performance assessment, the CES recommends, for measuring DWSE concentrations for comparison with the 8h-OEL values established by the CES, the following sampling devices for the inhalable and respirable fractions, keeping in mind their specific limitations of use stated in the following tables. These measurement methods are classified in Category 2 and considered as indicative and requiring verification of their performance for their intended environment of use.**

**Table 2: Methods recommended for measuring DWSE with regard to the 8h-OEL defined for the inhalable fraction**

Sampling device	Protocols / References	Classification			Limitations	Recommended sampling time to cover 0.1 to 2*8h-OEL
		Samples (*)	Gravimetry	Global method		
Button	FD CEN/TR 15230 HSE MDHS 14-4, INSHT CR 003 A06, INSHT MTA/MA 014/A11 Li <i>et al.</i> , 2000 Aizenberg, Grinshpun <i>et al.</i> , 2000b Aizenberg <i>et al.</i> , 2001 Witschger <i>et al.</i> , 2004 Görner <i>et al.</i> , 2010 Sleeth <i>et al.</i> , 2012	2	1B	2	Greater over-sampling at low wind speeds Slight increase in sampling efficiency at wind speeds $\geq 1 \text{ m}\cdot\text{s}^{-1}$ Gravimetry: use of 25 mm PVC filters	<b>Need to collect two 4h samples</b>
CFC + internal capsule	NIOSH 0501, INRS MétroPol M-274, INRS MétroPol cassette, NF X43-257 Görner <i>et al.</i> , 2010	2	1A	2	Effect of inclination not studied <b>Underestimation of the conventional inhalable fraction above 40-50 <math>\mu\text{m}</math></b> Lower bias compared with the conventional inhalable curve at low wind speeds Sampling efficiency has not been studied for wind speeds $\geq 1 \text{ m}\cdot\text{s}^{-1}$	8h
CIP 10-I-V2	MDHS 14-4 INSHT CR-03/2006 FD CEN/TR 15230 IRSST MA-373 INSHT MTA/MA_014_A11 Görner <i>et al.</i> , 2009 Görner <i>et al.</i> , 2010	2	1A	2	<b>Underestimation of the conventional inhalable fraction above 40-50 <math>\mu\text{m}</math></b> Decrease in sampling efficiency at low wind speeds (greater underestimation) Increase in sampling efficiency at $1 \text{ m}\cdot\text{s}^{-1}$ (decrease in bias with regard to the conventional inhalable fraction) Gravimetry: <b>one-tenth of the 8h-OEL is reached</b>	<b>8h</b>

Sampling device	Protocols / References	Classification			Limitations	Recommended sampling time to cover 0.1 to 2*8h-OEL
		Samples (*)	Gravimetry	Global method		
					with the lower limit of the LQ range	
GSP-3.5 / CIS	BIA 7284 DFG MAK sampling and determining aerosols FD CEN/TR 15230 MDHS 14-4 INSHT CR-03/2006 INSHT MTA/MA_014_A11 Kenny <i>et al.</i> , 1997 Li <i>et al.</i> , 2000 Aizenberg, Grinshpun <i>et al.</i> , 2000a Aizenberg, Grinshpun <i>et al.</i> , 2000b Aizenberg <i>et al.</i> , 2001 Sleeth <i>et al.</i> , 2012	2	1B	2	<b>Underestimation of the conventional inhalable fraction above 40-50 µm</b> Greater over-sampling at low wind speeds At wind speeds $\geq 1$ m·s <sup>-1</sup> , increase or decrease in sampling efficiency depending on the orientation (facing the airflow or averaged) Potentially high deposition on walls for the highest aerodynamic equivalent diameters	<b>Need to collect two 4h samples</b>
IOM	MDHS 14-4 INSHT CR-03/2006 FD CEN/TR 15230 IRSST MA-373 INSHT MTA/MA_014_A11 Kenny, Aitken, <i>et al.</i> , 1997 Kenny <i>et al.</i> , 1999 Li <i>et al.</i> , 2000 Aizenberg, Grinshpun, <i>et al.</i> , 2000a Aizenberg, Grinshpun, <i>et al.</i> , 2000b Aizenberg <i>et al.</i> , 2001 Paik <i>et al.</i> , 2004 Görner <i>et al.</i> , 2009 Witschger <i>et al.</i> , 2004 Görner <i>et al.</i> , 2010 Sleeth <i>et al.</i> , 2012	2	1A	2	Possible capture of large particles emitted in certain processes via the opening of the device Over-sampling of particles with diameters above 70 µm Greater over-sampling at low wind speeds At wind speeds $\geq 1$ m·s <sup>-1</sup> , increase or decrease in sampling efficiency depending on the orientation (facing the airflow or averaged)	8h
7-hole	HSE MDHS 14/4 Kenny, Aitken, <i>et al.</i> , 1997	2	1A	2	<b>Slight underestimation of the conventional inhalable fraction</b>	8h



Sampling device	Protocols / References	Classification			Limitations	Recommended sampling time to cover 0.1 to 2*8h-OEL
		Samples (*)	Gravimetry	Global method		
	Kenny <i>et al.</i> , 1999 Li <i>et al.</i> , 2000				above 30 µm at 0.5 m·s <sup>-1</sup> but overestimation at lower wind speeds Overestimation when oriented facing the airflow	
(*) compliance of the sampling device for the conventional inhalable fraction						

**Table 3: Methods recommended for measuring DWSE with regard to the 8h-OEL defined for the respirable fraction**

Sampling device	Protocols / References	Classification			Limitations	Recommended sampling time to cover 0.1 to 2*8h-OEL
		Samples (*)	Gravimetry	Global method		
DO cyclone	MétoPol Cyclone (2019) INSHT MTA-MA014/A11 OSHA PV 2121 NIOSH 0600 NF X 43-259 FD CEN 15230 Lidén & Kenny, 1993 Kar <i>et al.</i> , 1995 Gautam <i>et al.</i> , 1997 Chen <i>et al.</i> , 1999; Tsai <i>et al.</i> , 1999 Görner <i>et al.</i> , 2001	2	2	2	Overestimation for particle sizes of 1 to 4 µm and <b>underestimation for particle sizes of 4 to 10 µm</b> ↓ D <sub>50</sub> and ↑ bias with high wind speeds and 90 and 180° orientations of the device Issue of deposition on walls, effect of electrostatic charges Gravimetry: <b>optimisation of the LQ values necessary to reach 0.1*8h-OEL</b>	Need to collect one 8h sample
AI cyclone	NIOSH 0600 FD CEN 15230 Chen <i>et al.</i> , 1999 Tsai <i>et al.</i> , 1999 Görner <i>et al.</i> , 2001	2	1A	2	Overestimation for particle sizes of 1 to 4 µm and <b>underestimation for particle sizes of 4 to 10 µm</b> No influence of deposition on walls, or of the type, concentration or electrostatic charge of the aerosol	8h
GS3 cyclone	MétoPol Cyclone (2019) HSE MDHD 14/4 FD CEN 15230 INSHT MTA-MA014/A11 Gautam <i>et al.</i> , 1997	2	1B	2	Overestimation for particle diameters below 4 µm and <b>underestimation for particle diameters of 4 to 10 µm</b> No difference depending on the device's orientation ↑ bias at a very high wind speed No effect of deposition on walls or of electrostatic charges	<b>Need to collect two 4h samples</b>

Sampling device	Protocols / References	Classification			Limitations	Recommended sampling time to cover 0.1 to 2*8h-OEL		
		Samples (*)	Gravimetry	Global method				
	Chen <i>et al.</i> , 1999							
HD cyclone	FSP 10	IFA 6068 DFG MAK Lee <i>et al.</i> , 2010	2	1B	2	Pressure drop due to the high flow rate  Overestimation for particle diameters below 4 µm and <b>underestimation for particle diameters of 4 to 10 µm</b>  No studies concerning high wind speeds or the influence of the device's orientation, relative humidity, or the type, concentration and electrostatic charge of the aerosol Filter + cassette weighing recommended	Need to collect two 4h samples	
	SIMPEDS – FSP2	NIOSH 0600 HSE MDHS 14/4 Görner <i>et al.</i> , 2001 Liden & Kenny, 1993	2					-
	SKC Plastic	SKC Plastic cyclone notice (2019)	2					-
GK cyclone	GK2.69	HSE MDHS 14/4 FD CEN 15230 Kenny & Gussman, 1997 Lee <i>et al.</i> , 2010	2	1B	2	Pressure drop due to the high flow rate  Overestimation for particle diameters below 4 µm and <b>underestimation for particle diameters of 4 to 10 µm</b>  No studies concerning high wind speeds or the influence of the device's orientation, relative humidity, or the type or concentration of aerosol	Need to collect two 4h samples	
	GK4.162	Thorpe, 2011	2	1B	2			
(*) compliance of the sampling device for the conventional respirable fraction								

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